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APPLICATION FOR
UNITED STATES PATENT
IN THE NAMES OF

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ASSIGNED TO

PENJET CORPORATION

FOR

ENGINE AND DIFFUSER FOR USE WITH A NEEDLE-LESS INJECTOR

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TITLE OF INVENTION:

ENGINE AND DIFFUSER FOR USE WITH A NEEDLE-LESS INJECTOR

RELATED APPLICATIONS

a1 This application is related to U.S. patent application serial No. 09/834,476, filed April 13, 2001. This application also generally relates to [atty. docket No. 69816-0277436], which is a divisional application of U.S. patent application serial No. 09/566,928, filed May 6, 2000, now U.S. Patent No. ______. Further, this application generally relates to U.S. patent application serial No. 09/215,769, filed December 19, 1998, now U.S. Patent No. 6,063,053, which is a continuation of U.S. patent application serial No. 08/727,911, filed October 9, 1996, now U.S. Patent No. 5,851,198, which is a continuation-in-part of U.S. patent application serial No. 08/719,459, filed September 25, 1996, now U.S. Patent No. 5,730,723, which is a continuation-in-part of U.S. patent application serial No. 08/451,470, filed October 10, 1995, now abandoned. This application is also generally related to U.S. patent application serial No. 09/433,916, filed November 3, 1999, now U.S. Patent No. 6,302,160, which is a continuation-in-part of U.S. patent application serial No. 09/192,145, filed November 14, 1998, now U.S. Patent No. 6,223,786. This application is further generally related to U.S. patent application serial No. 09/192,079, filed November 14, 1998, now U.S. Patent No. 6,080,130, and to U.S. patent application serial No. 09/808,511, filed March 14, 2001.

FIELD OF THE INVENTION

This invention relates to needle-less injectors, and, in particular, to engine and diffuser assemblies for use with modular gas-pressured needle-less injectors and methods of performing needle-less injections using the same.

BACKGROUND OF THE INVENTION:

Traditionally, fluids such as medications are injected into patients, either subdermally or intradermally, using hypodermic syringe needles. The body of the syringe is filled with the injectable fluid and, once the needle has pierced the patient's skin, the syringe plunger is depressed so as to expel the injectable fluid out of an opening in the needle. The person performing the injection is usually a trained medical services provider, who manually inserts the hypodermic needle between the layers of a patient's skin for an intradermal injection, or beneath the skin layers for a subcutaneous injection.

Intradermal or subdermal delivery of a medication through the use of a hypodermic needle requires some skill and training for proper and safe administration. In addition, the traditional method of intradermal injections requires actual physical contact and penetration of a needle through the skin surface of the patient, which can be painful for the patient. Traditional needle injectors, such as hypodermic syringes, are also expensive to produce and difficult to use with prepackaged medication doses. Needle injectors also suffer from increased danger of contamination exposure to health care workers administering the injections, and to the general public when such injectors are not properly disposed of.

Jet injectors are generally designed to avoid some or all of these problems. However, not only are conventional jet injectors cumbersome and awkward, but, existing conventional jet injectors are only capable of subcutaneous delivery of a medication beneath the skin layers of a patient. Conventional jet injectors are also somewhat dangerous to use, since they can be discharged without being placed against the skin surface. With a fluid delivery speed of about 800 feet per second (fps) and higher, a conventional jet injector could injure a person's eye at a

distance of up to 15 feet. In addition, jet injectors that have not been properly sterilized are notorious for creating infections at the injection site. Moreover, if a jet injector is not positioned properly against the injection site, the injection can result in wetting on the skin surface. Problems associated with improper dosage amounts may arise as well, if some portion of the fluid intended for injection remains on the skin surface following an injection, having not been properly injected into and/or through the skin surface.

Typically, needle-less medication injectors use either an expansion spring or a compressed inert gas to propel the fluid medication (via a push rod plunger) through a small orifice (an injector nozzle) which rests perpendicular to and against the injection site. The fluid medication is generally accelerated at a high rate to a speed of between about 800 feet per second (fps) and 1,200 fps (approximately 244 and 366 meters per second, respectively). This causes the fluid to pierce through the skin surface without the use of a needle, resulting in the medication being deposited in a flower pattern under the skin surface.

It should be noted, however, that compression spring propelled jet injectors do not offer linear delivery speeds (constant speed of the fluid being injected). In addition to this problem, spring propelled jet injectors with weak (e.g., deteriorated) springs often slow fluid delivery speed down while an injection is being administered, resulting in improper fluid penetration. Reduced speed of the fluid can cause improper dosing and bruising at the injection site when the injection surface is the skin of a human recipient.

In a jet injector, if the inert gas is not quickly and properly expelled, fluid may be improperly injected, as with those devices employing a compression spring. Conventional disposable needle-less injectors, such as those shown in U.S. Patent No. 4,913,699 to Parsons and U.S. Patent No. 5,009,637 to Newman et al. show a gas-containing, breakable tube that is

shattered or cracked open by a side mounted trigger. Difficulties arise in the need to maintain tight tolerances on the breakable member, since minor changes in thickness can dramatically effect the pressure needed to deploy the gas from the gas chamber of the device. In addition, the broken shards of the breakable member are ejected at high speed when the gas is expelled and these shards can occasionally jam between the plunger driver and the housing, thereby preventing proper operation of the needle-less injector. Attempts to prevent small shards from being formed would obviate some of this potential, but tend to make activation of the device more difficult.

U.S. Patent No. 6,080,130, U.S. Patent No. 6,063,053, U.S. Patent No. 5,851,198 and U.S. Patent No. 5,730,723 describe needle-less injectors incorporating a gas power source, thus obviating some of the limitations inherent in compression spring injectors and addressing many of the concerns of conventional jet injectors. The injectors described therein have a pre-filled and self-contained compressed gas for providing pressure to inject medication into the skin surface of a patient without the use of a needle.

Gas power sources for needle-less injectors that employ either pop valves or breakaway tab valves to release the inert gas stored in their respective gas chambers, however, may only be opened once, thereby presenting difficulty with regard to quality control testing measures. Further, operation of many injectors requires a user to depress a trigger, relying mainly on resistance force from the injection surface to initiate an injection. Where the underlying surface is sensitive, applying such pressure may not be advantageous. Further, if the injection surface is slippery such a device may slide out of place during an injection rendering its use potentially injurious and possibly resulting in improper fluid delivery.

U.S. patent application serial No. 09/834,476 describes a needle-less injector that includes an engine assembly fit with a diffuser. The diffuser includes a number of channels which allow gas deployed from the engine to pass from the storage canister through the diffuser to the distal end of a driver, forcing the driver forward and causing liquid to be expelled from the injector. The number, orientation and size of these channels may be selected to optimize delivery parameters of a particular injection fluid. However, the use of channels in a diffuser may result in excessive back pressure upon deployment of gas from the engine. Consequentially, optimal gas flow may not be achieved, and the injector may not operate in the most efficient manner possible. Suboptimal gas flow may result in a comparatively slower injection; shallower liquid penetration into the patient; and moderate pain upon administration of an injection

U.S. patent application serial No. 09/834,476 further describes grips configured upon the engine assembly that mechanically interlock with a diffuser. The interlocking action occurs upon administration of an injection, as the engine assembly travels axially forward relative to the diffuser, which remains stationary. A user must apply a significant degree of mechanical force to cause this interlocking action to take place. Moreover, upon mechanical interaction of the grips and diffuser, an unpleasant "clicking" sound may be heard.

SUMMARY OF THE DISCLOSURE

It is therefore an object of an embodiment of the instant invention to provide gas-pressured needle-less injectors that obviate, for practical purposes, the above-mentioned limitations.

In one embodiment of the instant invention, a needle-less injector suitable for injecting fluid through an injection surface includes a housing, a trigger, an engine, a diffuser, and a

driver. The housing contains a fluid and the engine contains a compressed gas. Upon application of a sufficient amount of force to the trigger, the compressed gas is released from the engine forcing the driver through the interior of the housing, expelling the fluid from the housing at a speed sufficient to pierce an injection surface.

In another embodiment of the instant invention, a diffuser suitable for use with a needle-less injector includes an unobstructed air passage that may further include aerodynamic fins. The aerodynamic fins facilitate in the creation and maintenance of air flow with negligible back pressure when compressed gas is forced through the unobstructed air passage of the diffuser.

In another embodiment of the instant invention, a needle-less injector suitable for injecting fluid through an injection surface includes an engine, a diffuser, and a driver. The diffuser may include an unobstructed air passage that may further include aerodynamic fins. The engine contains a compressed gas, and the aerodynamic fins facilitate in the creation and maintenance of air flow with negligible back pressure when compressed gas is forced through the unobstructed air passage of the diffuser.

In another embodiment of the instant invention, a needle-less injector suitable for injecting fluid through an injection surface includes an engine, a diffuser, and a driver. The diffuser may include an O-ring around its outer circumference. The engine contains a compressed gas, and the O-ring prevents undesirable leakage of gas through the space between the engine and the diffuser.

In another embodiment of the instant invention, the needle-less injector includes a mechanism for mitigating the kickback associated with releasing compressed gas from the engine. Grips may be included on the engine, mechanically coupling the engine to a diffuser that is affixed to the housing, thereby preventing the engine from separating from the housing upon

release of compressed gas from the engine. Retainer hooks on the interior of the trigger corresponding to latch retainer mechanisms on the exterior of the housing may also be used to prevent the engine from separating from the housing.

In yet another embodiment of the instant invention, the housing of the needle-less injector includes finger rests that provide stability in administering an injection and provide resistance to activate the needle-less injector. Thus, a user need not rely solely on resistance from the injection surface to initiate the administration of an injection. The finger rests may be included on opposing sides of the housing, designed to comfortably receive the fingers of a user without substantial slippage.

In yet another embodiment of the instant invention, the engine of the needle-less injector is fitted with a reusable valve. The valve may contain a rubber head that is held against a fixed element of the engine, such as an airtight ring, such that depression of the trigger separates the head from the fixed element, releasing the compressed gas from the engine and, further, forcing the driver to expel fluid from the housing. A spring may be included in the valve to help maintain a proper airtight seal with the canister holding the compressed gas.

In yet another embodiment of the instant invention, a safety clamp is included on the exterior of the housing of the needle-less injector, preventing accidental activation of the device. The safety clamp must be removed prior to use and may be made of a sufficiently elastic material such that a user need only deform the clamp, aided by grips included thereon, to remove the clamp from the housing.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1a-1c illustrate a needle-less injector in accordance with an embodiment of the instant invention. FIG. 1a is a side perspective view in partial breakaway prior to administration

of an injection, shown at 0° rotation about the central axis of the injector, FIG. 1b is a side cross-sectional view, the injector having been rotated 90° about the central axis, FIG. 1c is a side perspective view at 0° rotation about the central axis, and FIG. 1d is a side cross-sectional view after administration of an injection, shown at 90° rotation about the central axis of the injector.

FIGS.2a-2c illustrate the housing of a needle-less injector in accordance with an embodiment of the instant invention. FIG. 2a is a side perspective view at 180° rotation about the central axis of the injector, FIG. 2b is a proximate end perspective view and FIG. 2c is a distal end perspective view.

FIGS. 3a-c illustrate the ampoule cap of a needle-less injector in accordance with an embodiment of the instant invention. FIG. 3a is a side perspective view, FIG. 3b is a side cross-sectional view and FIG. 3c is a proximate end perspective view.

FIGS. 4a-c illustrate the plunger of a needle-less injector in accordance with an embodiment of the instant invention. FIG. 4a is a side perspective view, FIG. 4b is a side cross-sectional view and FIG. 4c is a proximate end perspective view.

FIGS. 5a-d illustrate the piston of a needle-less injector in accordance with an embodiment of the instant invention. FIG. 5a is a side perspective view, FIG. 5b is a side cross-sectional view, FIG. 5c is a proximate end perspective view and FIG. 5d is a distal end perspective view.

FIGS. 6a-b illustrate the diffuser of a needle-less injector with aerodynamic fins in accordance with an embodiment of the instant invention. FIG. 6a is a side perspective view and FIG. 6b is a side cross-sectional view.

FIGS. 7a-b illustrate the diffuser of a needle-less injector with aerodynamic fins in accordance with an embodiment of the instant invention. FIG. 7a is a proximate end perspective view and FIG. 7b is a distal end perspective view.

FIGS. 8a-d illustrate the trigger of a needle-less injector in accordance with an embodiment of the instant invention. FIG. 8a is a side perspective view at 0° rotation about the central axis of the trigger, FIG. 8b is a side cross-sectional view at 90° rotation, FIG. 8c is a proximate end perspective view and FIG. 8d is a distal end perspective view.

FIGS. 9a-b illustrate the safety clamp of a needle-less injector in accordance with an embodiment of the instant invention. FIG. 9a is a proximate end perspective view and FIG. 9b is a side perspective view.

FIGS. 10a-d illustrate the engine housing of a needle-less injector in accordance with an embodiment of the instant invention. FIG. 10a is a distal end perspective view, FIG. 10b is a side cross-sectional view, FIG. 10c is a proximate end perspective view and FIG. 10d is a side perspective view.

FIGS. 11a-c illustrate the valve body of a needle-less injector in accordance with an embodiment of the instant invention. FIG. 11a is a side perspective view, FIG. 11b is a side cross-sectional view, FIG. 11c is a proximate end perspective view.

FIGS. 12a-c illustrate the closing ferrule of a needle-less injector in accordance with an embodiment of the instant invention, prior to the closing ferrule being mechanically fitted around a valve body and an engine housing. FIG. 12a is a side perspective view, FIG. 12b is a side cross-sectional view and FIG. 12c is a proximate end perspective view.

FIGS. 13a-d illustrate the threaded valve stem guide of a needle-less injector in accordance with an embodiment of the instant invention. FIG. 13a is a side perspective view in

partial cross-section, FIG. 13b is a side cross-sectional view, FIG. 13c is a proximate end perspective view and FIG. 13d is a distal end perspective view.

FIGS. 14a-c illustrate the valve stem of a needle-less injector in accordance with an embodiment of the instant invention. FIG. 14a is a side perspective view, FIG. 14b is a side cross-sectional view prior to the distal end being shaped and FIG. 14c is a proximate end perspective view.

FIGS. 15a-b illustrate the valve spring of a needle-less injector in accordance with an embodiment of the instant invention. FIG. 15a is a side perspective view in the relaxed state, FIG. 15b is a side perspective view in the compressed state.

FIG. 16 is a graph depicting the velocity of the driver of an embodiment of the instant invention during administration of an injection.

FIGS. 17a-b illustrate the valve body and diffuser in accordance with various embodiments of the instant invention. FIG. 17a is a side cross-sectional view in partial breakaway of the valve body along with the diffuser and valve stem where the valve is in the closed position and FIG. 17b is a side cross-sectional view in partial breakaway of the valve body along with the diffuser and valve stem where an airtight ring is included therewith and the valve is in the open position.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the drawings for purposes of illustration, the invention is embodied in a gas-pressured needle-less injector. In preferred embodiments of the present invention, the gas-pressured needle-less injector is pre-loaded with fluid and is adapted for a single use. Preferably, the needle-less injector is for use with human beings or other animals. However, it will be

recognized that further embodiments of the invention may be used in other applications requiring needle-less injection, such as passing injectable materials through a porous membrane or the like.

Also, embodiments of the present invention may be used to inject other fluids or injectants such as proteins, vitamins, hormones, drugs, vaccines, medications, lyophilized medications, medication cocktails, or the like, and such are contemplated as being within the scope of the term "fluid" as used herein. In preferred embodiments, the fluids used in accordance with the present invention are de-gassed prior to filling into the needle-less injector or are of sufficient chemical properties such that the fluids de-gas immediately upon or soon after filling, as described in U.S. patent application serial No. 09/808,511, filed March 14, 2001. In either of such preferred embodiments, substantially no gas pocket develops in the interior cavity where the fluid resides during storage of the needle-less injector, prior to use.

For ease in describing the various elements of the instant invention, the following spatial coordinate system will apply thereto. As depicted in FIG. 1c, a central axis is defined through the length of a gas-pressured needle-less injector **100**. This central axis **1** has one terminus at the proximate end **2** of the needle-less injector **100**, defined as that end of the device in contact with an injection surface during normal operation of the injector. The other terminus of the central axis is at the distal end **3** of the injector **100**, defined as that end of the device furthest from the injection surface when the injector is positioned perpendicular to the injection surface. Thus, various elements of the device of the instant invention may be described with reference to their respective proximate and distal portions, as well as their central axes.

As depicted in FIG. 1, a gas-pressured needle-less injector **100** includes a housing **201**. The housing **201** may be of any suitable shape, though in preferred embodiments it is roughly cylindrical about the central axis. The housing **201** preferably has a varying interior diameter

along its length to accommodate the elements that reside and operate therein when the injector **100** is fully assembled. The housing **201** depicted in FIG. 2a has four such interior diameters: an ampoule diameter **202**, a piston diameter **203**, a diffuser diameter **204** and an engine diameter **205**, respectively. Embodiments of the instant invention may have an ampoule that is a mechanical element separate and distinct from the housing **201**, yet the housing **201** may act as an ampoule for various purposes such as filling with fluid.

The exterior portion **206** of the proximate end surface of the housing **201** may be flat, though in preferred embodiments it is of a shape that maximizes injector efficacy. Efficacy is optimal when substantially all fluid contained in the injector **100** is delivered through the injection surface, leaving substantially no fluid on either the injection surface or the exterior portion **206** of the proximate end surface of the housing **201** after an injection is complete (see FIG. 1d). To that end, in the embodiment depicted in FIG. 2a, the exterior portion **206** of the proximate end of the housing **201** is adapted to pinch and stretch the surface (e.g., skin surface) through which an injection is to be administered, as the exterior portion **206** of the proximate end surface of the housing **201** is brought into contact with an injection surface. Thus, the exterior portion **206** of the proximate end of the housing **201** preferably has a conical shape about the central axis, and further possesses an elevated rim **207** around its circumference.

The interior portion **208** of the proximate end of the housing **201** may be of any appropriate shape. It may conform roughly to the shape of the exterior portion **207**, or have a design independent thereof. In one embodiment, the interior portion **208** is flat, though preferably, as depicted in FIG. 2a the interior portion **208** is roughly conical, with at least one orifice **209** at or near the vertex **210**. The needle-less injector **100** depicted in FIG. 1 is shown with only one orifice.

The at least one orifice **209** provides fluid communication between the interior **214** of the housing **201** and the surface through which an injection is administered. The number of orifices **209** may be varied depending on the delivery parameters of the fluid to be injected. One such parameter is the depth to which a fluid must penetrate a recipient's tissue, when the device is used for the injection of a medicament into a human being. For example, in one embodiment it may be desirable to inject a fluid just beneath the outermost skin layers of a recipient, and multiple orifices may best suit that end. Alternatively, a single orifice may be most desirable for an injection that requires deeper penetration for maximum drug efficacy.

An exhaust passage **211** may be created through the housing **201**, from the interior wall **212** to the exterior wall **213**, preferably within the section of the housing **201** of ampoule diameter **202**. The exhaust passage **211** allows gas to vent from the interior **214** of the housing **201** preferably only after an injection has been administered. Thus, most preferably, the exhaust passage **211** is located at a point in the housing **201** at, or immediately distal to, the location of the piston **500** (see FIGS. 1d) after administration of an injection. In these most preferred embodiments, gas may not vent from the interior **214** of the housing **201** through the exhaust passage **211** until after substantially all fluid contained in the housing **201** has been discharged from the needle-less injector **100**, with the piston **500** at rest in its final position. However, latent air that is present in the space between the piston **500** and the interior wall of the housing **201** prior to administration of an injection may seep through the exhaust passage **211** both prior to and during administration of an injection.

Fluid stored in the needle-less injector **100**, prior to administration of an injection, is preferably contained in the interior **214** of the housing **201** in the region bounded by the interior

portion **208** of the proximate end of the housing **201**, the interior wall **212** of the housing **201** and the proximate end **403** of the plunger **400** (see FIG. 1a and 2a).

As depicted in FIG. 2a, the housing **201** may further include finger rests **215**. In preferred embodiments, two such finger rests **215** are formed on the exterior wall **213** of the housing **201** at opposing locations. Most preferably, the finger rests **215** are located directly opposite one another. In preferred embodiments, each finger rest **215** has an arc **216** on the proximate side thereof to accommodate proper finger placement for either self-administration of an injection or assisted administration by a health care professional or the like. In the most preferred embodiments, the arcs **216** of the finger rests **215** further contain a non-slip, textured surface **217** (see Fig. 2b).

When the needle-less injector **100** is used by an individual performing self-administration of an injection, the individual's thumb and middle finger may be placed in the arcs **216** of the finger rests **215** on opposing sides of the housing **201** for stabilization of the device, with the index finger operably placed against the trigger **800** at the distal end of the injector **100**. Another manner in which a user may perform self-administration of an injection, which is also the manner preferred when the needle-less injector **100** is operated by an individual other than the recipient of an injection, involves the index and middle fingers being placed in the arcs **216** of the finger rests **215** on opposing sides of the housing **201** for stabilization of the device, with the thumb operably placed against the trigger **800** at the distal end of the injector **100**.

The housing **201** may further contain at least one latch retainer mechanism **218** near the distal end. The at least one latch retainer mechanism **218** may be comprised of a single set of saw tooth ridges that encircle the exterior wall **213** of the housing **201** around its central axis. More preferably, there are two latch retainer mechanisms **218** each comprising a set of saw tooth

ridges **219**, disposed opposite one another on the exterior wall **213** of the housing **201**, though any appropriate number of latch retainer mechanisms **218** may be utilized. Preferably, as shown in FIG. 1b, the housing **201** further contains a clamp indentation **220** that is defined on its proximate end by a ridge **221** and on its distal end by the at least one latch retainer mechanism **218** and the proximate end of the trigger **800**.

The proximate end of the housing **201** may further be fit with an ampoule cap **300**, as depicted in FIG. 3, which serves to maintain sterility of the exterior portion **206** of the proximate end surface of the housing **201** while the needle-less injector **100** is stored. Further, when de-gassed fluids are used in accordance with the present invention, the ampoule cap **300** provides the requisite airtight seal between the at least one orifice **209** in the proximate end of the housing **201** and the local atmosphere, such that the de-gassed fluids may remain gas-free during storage. Referring again to FIG. 3, the interior **301** of the ampoule cap **300** is preferably designed to conform substantially to the exterior surface **206** of the proximate end of the housing **201**, while the exterior **302** of the ampoule cap **300** may be of any convenient configuration. The ampoule car **300** may be constructed of any suitably non-toxic, malleable material, such as rubber.

As depicted in FIG. 4, the housing **201** may be fit with a plunger **400**. Preferably, the plunger **400** is pressure-fit within the housing **201**, as its diameter is equivalent to or slightly greater than the ampoule diameter **202** of the housing **201**. The plunger **400** is preferably constructed of a sufficiently elastic material such that the pressure-fit creates an air and fluid-tight seal with the interior wall **212** of the housing **201**. The plunger **400** is preferably cylindrical to mirror the shape of the interior wall **212** of the housing **201**, though other shapes may be suitable especially where the interior wall **212** of the housing **201** is not cylindrical. Moreover, the wall **401** of the plunger **400** may have multiple ridges **402** disposed thereupon. Preferably,

there are at least two such ridges **402**, and most preferably there are three ridges **402**. These ridges **402** provide stability to the plunger **400** such that its direction of travel during administration of an injection remains substantially linear along the central axis, without rotational motion around any axis other than the central axis.

The proximate end **403** of the plunger **400** may be of any suitable shape, including a flat surface, though in preferred embodiments it roughly mirrors the shape of the interior wall **208** of the proximate end of the housing **201**. However, the elastic properties of the plunger material may allow the proximate end **403** of the plunger **400** to conform to the shape of a surface different than its own when mechanically forced against such a surface. Thus, the shape of the proximate end **403** of the plunger **400** need not mirror the shape of the interior wall **208** of the proximate end of the housing **201**, yet the plunger proximate end **403** may conform to the shape of the interior wall **208** when forced against it during or after an injection is administered. In most preferred embodiments, however, the proximate end **403** of the plunger **400** is roughly conical in shape.

The distal end **404** of the plunger **400** may similarly be of any suitable shape, and is received by the proximate end of the piston **500**. In preferred embodiments, the plunger **400** is symmetrical in shape along a plane perpendicular to the central axis, for ease in manufacturing. Thus, in preferred embodiments, the distal end **404** of the plunger **400** is roughly conical in shape.

The housing **201** may be fit with a piston **500**, as depicted in FIG. 5. The piston **500** preferably is of roughly cylindrical shape along the length of its central axis with a flared portion **501** toward its distal end, though other shapes may be appropriate especially in those embodiments where the interior wall **212** of the housing **201** is non-cylindrical. Preferably, the

proximate end **502** of the piston **500** is shaped such that it mechanically receives the distal end **404** of the plunger **400**. Thus, in most preferred embodiments, the proximate end **502** of the piston **500** is a roughly conical indentation. In preferred embodiments, the piston **500** further includes a chamber **503** that extends from the vertex of the conical indentation **502** along the central axis of the piston **500**.

The exterior of the distal section of the piston is preferably a flared portion **501**, terminating in an expansion cup rim **504**. In most preferred embodiments, the distal section of the piston further has a hollow expansion cup **505**. This expansion cup **505** is not in gaseous communication with the chamber **503** that extends from the proximate end **502** of the piston **500** along the piston central axis, as the chamber **503** does not extend entirely through the piston **500** to the expansion cup **505**.

Referring to FIGS. 2a and 5, the distal section of the piston **500** may be pressure-fit within the portion of the housing **201** of piston diameter **203**, such that the diameter of the expansion cup rim **504** of the piston **500** is substantially equivalent to the piston diameter **203** of the housing **201**. Alternatively, the diameter of the expansion cup rim **504** may be slightly less than the piston diameter **203** of the housing **201**. During use of the needle-less injector **100**, the expansion cup **505** may expand radially due to the force of compressed gas pushing upon it. This serves to optimize the performance of the piston **500**, as a substantially airtight seal is thus formed between the expansion cup rim **504** and the interior wall **212** of the housing **201**.

The housing **201** may be fit with a diffuser **600**, as depicted in FIG. 6. The diffuser **600** is preferably affixed to the housing **201** along the interior wall **212** thereof at the portion of diffuser diameter **204**. Affixing may be performed by high frequency welding or other suitable

means. Most preferably, the diffuser **600** is affixed to the housing **201** only after the plunger **400** and piston **500** have been fit within the housing **201**.

The diffuser **600** may preferably further contain an unobstructed, doughnut-shaped air passage **601** that provides gaseous communication between the distal end **602** of the diffuser **600** and the proximate end of the diffuser **603**. More preferably, the unobstructed, doughnut-shaped air passage is fitted with aerodynamic fins **608**. The aerodynamic fins **608** aid in the creation and maintenance of substantially laminar gas flow through the diffuser **600**, as opposed to potentially turbulent flow, which may result from the use of channels in the diffuser. Where channels are employed, a surface resides in the area of the unobstructed, doughnut-shaped air passage, and holes (or, channels) are bored therethrough. The remaining area of the surface is aerodynamically significant, as it obstructs the axial flow of gas, creating turbulence and, correspondingly, wasting valuable energy in the system. Wasted energy may equate to a slower injection; comparatively shallow fluid penetration into the patient; and moderate pain upon administration of an injection. Laminar gas flow effects a more efficient use of the pressurized gas in the engine and obviates other potential shortcomings associated with the use of channels. Thus, the unobstructed air passage **601** with accompanying aerodynamic fins **608** is the most preferred embodiment of the diffuser **600** of the present invention, and may function to maintain the optimal fluid delivery profile illustratively indicated in Fig. 16.

As depicted in Fig. 16, optimal delivery may occur when the velocity of the driver almost immediately reaches a maximum velocity upon the beginning of administration of a needle-less injection. The driver then preferably travels at this maximum velocity until the injection is completed, at which point velocity almost immediately returns to zero, as the driver most preferably comes into contact with the proximate end of the housing. This optimal delivery

profile may be achieved by employing fins **608** in the unobstructed air passage **601** of a preferred diffuser **600** in accordance with embodiments of the instant invention.

As depicted in FIG. 7, each aerodynamic fin **608** is preferably substantially flat through its body **609**, while reaching a sharp edge on its distal end **610** and terminating in a rounded edge on its proximate end **611**. The fins **608** are most preferably oriented such that the flat body surface **609** runs parallel to the direction of axial gas flow through the diffuser **600**.

The diffuser **600** may be configured to include a variety of arrangements and/or number of aerodynamic fins **608**, and each is considered as being within the scope of the instant invention. For instance, any number of aerodynamic fins **608** may be included in the diffuser **600**, depending upon the desired flow characteristics of gas within the injector, and corresponding delivery parameters of the fluid contained therein. Preferably there are at least two aerodynamic fins **608**, and most preferably there are three aerodynamic fins **608** situated equidistant from one another about the central axis, though the fins **608** may be arranged in other configurations in alternate embodiments. Further, the aerodynamic fins **608** may be of different size and shape from one another or from that illustratively depicted in the preferred embodiments herein.

Referring to FIG. 6b, a valve stem support depression **604** may further be included on the distal end **602** of the diffuser **600**, located at the diffuser central axis member **612**. The diffuser central axis member **612** is preferably bullet-shaped at its proximate end **613** to aid in creating and maintaining a substantially laminar flow, and most preferably, the proximate end of the central axis member **613** extends beyond the proximate edges **611** of the aerodynamic fins **608**. The diffuser **600** may further contain a locking ring **605** around its outer circumference.

Preferably the locking ring **605** is angled on its distal surface **606**, but is flat on its proximate surface **607**.

The diffuser **600** may further include an O-ring depression **615** about its distal circumference (see Fig. 6a). Preferably, an O-ring **614** resides therein (see Fig. 17). The O-ring **614** prevents the leakage of gas through the small space between the exterior of the distal end of the diffuser **600** and the diffuser-receiving chamber **1110** of the valve body **1100** illustratively depicted in FIG. 11. Moreover, the inclusion of O-ring **614** permits a needle-less injector to operate in silence, as the "popping" sound normally associated with evacuation of gas through a space blocked by O-ring **614** is eliminated.

The diffuser **600** may further include a knife-edge of material **616** around the circumference of its proximate end **603** (see Fig. 6b). The knife-edge of material preferably deforms during assembly of the needle-less injector **100**, as it may provide filler material for the ultrasonic welding of the diffuser **600** to the inside surface of the housing **201** at an internal ledge **223** (see FIG. 2a). Thus, after affixing the diffuser **600** to the housing **201**, the knife-edge of material **616** most preferably is no longer in its original configuration, having been permanently deformed and utilized as a bonding material. Though ultrasonic welding is the most preferred means for affixing the diffuser **600** to the housing **201**, other suitable methods may be employed, and in such methods a knife-edge of material **216** may not be desirable. However, these methods are contemplated as being within the scope of the present invention.

The housing **201** may further be fit with a trigger **800**, as depicted in FIG. 8. The trigger **800** is preferably roughly cylindrical, to match the shape of the exterior wall **213** of the housing **201**. The distal end of the trigger **800** may have a depression **801** therein, and in preferred

embodiments this depression **801** may further be textured (see Fig. 8d) for non-slip finger or thumb placement during operation of the needle-less injector **100**.

The trigger **800** preferably contains at least one retainer hook mechanism **802** used both for securing the trigger **800** to the housing **201** and for mitigating the kickback associated with deploying the compressed gas stored in the engine housing **1000**. Without such a safety feature, the force created by release of gas stored in the engine housing **1000** may cause the engine assembly to separate from the remainder of the needle-less injector **100**, potentially resulting in both an improper injection and injury to the user.

The at least one retainer hook mechanism **802** operably mates with the at least one latch retainer mechanism **218** located near the distal end of the housing **201** as the retainer hook **803** at the proximate end of the retainer hook mechanism **802** locks around consecutive saw tooth ridges **219** that preferably comprise the latch retainer mechanism **218** (see Fig. 2a). In preferred embodiments, there are two retainer hook mechanisms **802**, located opposite one another on the trigger **800**, that spatially correspond to two latch retainer mechanisms **218** on the exterior wall **213** of the housing **201**.

The at least one retainer hook mechanism **802** and at least one latch retainer mechanism **218** preferably prevent the trigger **800** from rotating about its central axis. In a most preferred embodiment, the sides **804** of the at least one retainer hook mechanism **802** fit around the sides **222** of the at least one latch retainer mechanism **218**, preventing such rotation.

The housing **201** may further be fit with a safety clamp **900**, as depicted in FIG. 9. The safety clamp **900** prevents the needle-less injector **100** from being discharged accidentally. The safety clamp **900** is preferably roughly semi-cylindrical in shape to conform to the exterior wall **213** of the housing **201**, and resides around the exterior wall **213** of the housing **201** in the clamp

indentation **220** that is defined on its proximate end by a ridge **221** and on its distal end by the at least one latch retainer mechanism **218** and the proximate end of the trigger **800** (see FIG. 1b). The safety clamp **900** preferably does not completely encircle the housing **201**, but encircles from between at least half of the housing **201** to slightly less than the entire housing, allowing for easy removal while preventing the clamp **900** from simply falling off of the injector **100**. Most preferably, the safety clamp **900** is constructed of a sufficiently elastic material such that temporarily deforming the clamp **900** permits removal thereof from the exterior wall **213** of the housing **201**. To aid in this removal, a grip **901** and feet **902** may be included on the safety clamp **900**.

The housing **201** is preferably fit with an engine assembly **101**, as depicted in FIG. 1b. The engine assembly **101** may further contain an engine housing **1000**, as depicted in FIG. 10. The engine housing **1000** is preferably constructed of a material impermeable to a compressed gas stored therein, and has a hollow interior chamber **1003**. Most preferably, the engine housing **1000** is comprised of stainless steel or a similar metal. A compressed inert gas is preferably used to drive the needle-less injector **100** and is stored within the engine housing **1000** prior to use. The most preferred gas is carbon dioxide, though other suitable gases may be employed, as well. In most preferred embodiments, the engine assembly **101** is overcharged (i.e., excess compressed gas is stored therein) to allow for use at variable altitudes without hampering the performance characteristics of the needle-less injector **100**.

The engine housing **1000** is preferably roughly cylindrical in shape to match the interior wall **212** of the housing **201**, though alternate configurations may be utilized. Referring to FIG. 10, the engine housing **1000** may have a portion of wide diameter **1001** and a portion of small diameter **1002**, wherein the portion of small diameter **1002** is proximate to the portion of wide

diameter **1001**. The distal end of the engine housing **1000** may contain a circular depression **1004** and may rest against the trigger **800** (see FIG. 1b). The proximate end of the engine housing **1000** contains an opening **1005**, and in preferred embodiments, a closing ridge **1006** encircles the opening **1005**.

The engine assembly **101** preferably further contains a valve body **1100**, as depicted in FIG. 11. The valve body **1100** is preferably roughly cylindrical in its overall shape, and more preferably resides at least partially within the engine housing **1000**. Most preferably, the distal portion exterior surface **1114** of valve body **1100** is slightly conical in shape, to allow more space for gas to be contained within the engine housing **1000**. The valve body **1100** most preferably has a closing rim **1101** around its outer circumference that rests against the closing ridge **1006** encircling the opening **1005** of the proximate end of the engine housing **1000**. Most preferably, a closing ferrule **1200** is wrapped around both the closing rim **1101** and closing ridge **1006** to secure the valve body **1100** and engine housing **1000** to one another (see FIG. 1b).

The closing ferrule **1200** is shown in FIG. 12 prior to its distal portion **1201** being mechanically bent around the closing rim **1101** and closing ridge **1006**. The proximate portion **1202** of the closing ferrule **1200** is of substantially the same diameter as the exterior of the valve body **1100**, such that solely bending the distal portion mechanically couples the valve body **1100** to the engine housing **1000**. In FIG. 1, the distal portion **1201** of the closing ferrule **1200** is shown in the bent state.

The valve body **1000** preferably has a depression **1102** around its circumference adapted to fit a gasket **1103** (see FIG. 1b). The gasket **1103** provides an airtight seal between the engine housing **1000**, which contains the gas, and the valve body **1100**. This airtight seal avoids the undesirable leakage of gas from the interior of the engine housing **1000** to the local atmosphere.

This added leakage resistance helps boost the efficiency of the present invention, as more gas is retained and not lost to the local atmosphere.

Referring to FIG. 11, the interior of the valve body **1100** is preferably hollow and comprised of several distinct portions. The distal interior portion **1104** of the valve body **1100** may contain a screw thread engagement **1105**, preferably extending from the distal end of the valve body **1100** to the distal end of a first axial cavity **1106**. The first axial cavity **1106** may be bounded on its proximate end by a shoulder **1107** that separates this first axial cavity **1106** from a second axial cavity **1108**, which is preferably of smaller diameter than the first axial cavity **1106**. In preferred embodiments, the shoulder **1107** is an angled edge, and in some preferred embodiments, the angled edge has cylindrically disposed thereupon an airtight ring **1701** (see FIG. 17) to improve the seal between the shoulder **1107** and the valve head **1405**. Where an airtight ring **1701** is included, preferably a groove **1702** is circumferentially formed about the valve head **1405**, such that the valve head **1405** can properly mate with and form an effective airtight seal with the airtight ring **1701**.

Also in preferred embodiments, at least one valve stem guide **1109** protrudes from the wall of the second axial cavity **1108**. In a most preferred embodiment, there are at least three such valve stem guides **1109** that serve to substantially prevent the valve stem **1400** from moving in any direction other than along the central axis of the needle-less injector **100** during administration of an injection.

The proximate end of the second axial cavity **1108** preferably terminates at a diffuser-receiving chamber **1110** that is of sufficient diameter such that it encircles a distal end **602** of the diffuser **600** (see Fig. 6). After administration of an injection with the needle-less injector **100**,

the distal end **602** of the diffuser **600** is most preferably at rest within the diffuser-receiving chamber **1110**.

The proximate end of the diffuser-receiving chamber **1110** preferably has at least one grip **1111** extending therefrom. Preferably, the at least one grip **1111** locks around another suitable element of a needle-less injector **100** as the gripping element **1112** is situated on the interior side of the grip **1111**. In alternative embodiments, however, the at least one grip **1111** may lock within another element, as the gripping element **1112** may be disposed on the exterior side of the grip **1111**. In most preferred embodiments, there are two grips **1111** disposed opposite one another each of which contains a gripping element **1112** situated on the interior side of the grip **1111** . In these most preferred embodiments, the two grips **1111** are slid over and lock around the locking ring **605** of the diffuser **600** during manufacture of the injector. Thus, the grips **1111** need not be forced past the locking ring **605** by a user, since this can prove a difficult task for some. Also, this eliminates the "clicking" sound made by the grips **1111** as they pass over and lock around the locking ring **605** from being heard during administration of an injection. Further, the combination of a locking ring **605** and grips **1111** assists in mitigating the kickback associated with deploying the compressed gas stored in the engine assembly **101**, while also providing the added safety feature of maintaining the structural integrity of the injector **100**, should damage be caused to the valve body **1100** or engine housing **1000** by, for example, excessive heat that might otherwise cause the injector **100** to break apart.

The valve body **1100** preferably further contains a threaded valve guide **1300**, as depicted in FIG. 13. The threaded valve guide **1300** is preferably cylindrical in shape and threaded around its exterior wall **1301**, such that it may be screwed into the distal interior portion **1104** of the valve body **1100** by interacting with the screw thread engagement **1105**, which is preferably

of the same axial length as the exterior wall **1301** of the threaded valve guide **1300**. Also, the distal end of the threaded valve guide **1300** is preferably flush with the distal end of the valve body **1100** after the two are screwed together. Most preferably, the threading on the exterior wall **1301** of the threaded valve guide **1300** extends along the entirety of the exterior wall **1301** from the distal to the proximate end of the threaded valve guide **1300**. The threaded valve guide **1300** may also contain a cylindrical interior cavity **1302** that is unobstructed at the proximate end. The distal end, however, is preferably partially covered with a valve stem guide pane **1303**. The valve stem guide pane **1303** preferably provides at least one vent **1304** allowing gaseous communication between the interior cavity **1302** of the threaded valve guide **1300** and the hollow interior chamber **1003** of the engine housing **1000** at the distal end of the threaded valve guide **1300**. Also preferably, the valve stem guide pane **1303** includes a hole **1305** at the central axis slightly larger in diameter than the valve stem **1400** that resides therein. Most preferably, the valve stem guide pane **1303** further includes a spring seat **1306** on its proximate surface that is comprised of at least one ridge **1307** that maintains the valve spring **1500** in proper position.

The valve body **1100** preferably further contains a valve stem **1400**, as depicted in FIG. 14. The valve stem **1400** is preferably comprised of a substantially cylindrical rod **1401** having a proximate end **1402** which is flat and a distal end **1403** which is preferably pressed or hammer-forged. The distal end **1403** is shown after hammer-forging in FIG. 14a and prior to hammer-forging in FIG. 14b. Most preferably, there is also included a spring ridge **1404** that extends radially from the rod **1401**, and a roughly conical valve head **1405** affixed to the proximate and exterior surfaces of the spring ridge **1404** as well as that portion of the rod **1401** immediately proximate to the spring ridge **1404**. Most preferably, the valve head **1405** is comprised of a rubber material such as silicon-based or butyl-based rubber that is sufficiently malleable for use

in accordance with the needle-less injector **100**. Butyl-based rubber is most preferred, and is similarly most preferred for use in the airtight ring **1701** and O-ring **614**. In most preferred embodiments, the angle between the proximate surface of the valve head **1405** and the central axis is substantially similar to the angle of the shoulder **1107** located between the first axial cavity **1106** and second axial cavity **1108** of the valve body **1100**.

The valve body **1100** may further contain a valve spring **1500**, as depicted in FIG. 15. The valve spring **1500** is preferably composed of wire and semi-conical in shape, wherein the proximate end **1501** is smaller in diameter than the distal end **1502**. The proximate end **1501** of the valve spring **1500** preferably rests against the distal surface of the spring ridge **1404** on the valve stem **1400**, while the distal end **1502** of the valve spring **1500** preferably rests against the proximate surface of the valve stem guide pane **1303** and is held in place radially by the spring seat **1306**.

Furthermore, the valve of the instant invention may be repeatedly opened and closed without being destroyed, thus it may be inspected for quality control determinations by opening and closing at least one time prior to the engine assembly **101** being filled with compressed gas. A faulty valve is a concern in any device employing such a mechanism, though it is of particular import in the context of a needle-less injector useful in medical applications, where such a faulty valve may result in the improper dosage of fluid.

Several mechanisms act to mitigate the kickback associated with releasing compressed gas from the engine housing. The grips on the valve body are operatively coupled with the locking ring on the exterior surface of the diffuser prior to administration of an injection, and the retainer hooks on the retainer hook mechanisms operatively lock at each successive saw tooth of the latch retainer mechanisms during administration of an injection. Such safety features not

only function to avoid potential injury, but further ensure proper delivery of fluid through an injection surface.

EXAMPLE

Operation of a Needle-less Injector

Prior to use, a needle-less injector is assembled in accordance with the instant invention, all elements thereof being gamma sterilized with the exception of the engine assembly. The engine assembly is checked for quality control purposes by opening and closing the valve, and thereafter the engine housing is filled with a suitable compressed gas. The interior portion of the housing between the proximate end of the housing and the proximate end of the plunger is then filled with, in this example, 0.5 ml. of fluid. The needle-less injector is then assembled and stored for a prolonged period of time.

When ready for use (see FIG. 1a), the ampoule cap is removed from the proximate end of the housing by the user. Subsequently, the user also removes the safety clamp by bending and/or distorting the clamp. The user is performing self-administration of an injection and elects to employ the following configuration: the user's index and middle fingers are placed in the arcs of the finger rests for stabilization of the device, with the thumb operably placed against the trigger. The proximate end of the needle-less injector is then positioned roughly perpendicular to the injection surface.

The user then depresses the trigger until the proximate end of the trigger comes to rest against the ridge defining the proximate end of the clamp indentation. During this movement of the trigger, the retainer hook mechanisms and latch retainer mechanisms interact as the retainer hooks lock past consecutive saw teeth that comprise the latch retainer mechanisms.

Forward, axial movement of the trigger causes the engine housing, valve body and threaded valve guide to move, as well. The grips at the proximate end of the valve body have already locked around the locking ring of the diffuser prior to injection, but the distal portion of the diffuser slides through the diffuser-receiving cavity of the valve body at this point, with an airtight seal remaining in the space between the diffuser and valve body owing to the inclusion of the O-ring. Simultaneously, the valve stem moves along with the trigger, however, once it comes into mechanical contact with the valve stem support depression in the diffuser it remains stationary relative to the housing.

When the valve stem and diffuser come into mechanical contact, the valve spring is compressed and the valve opens as the valve head is separated from the shoulder residing between the first and second axial cavities of the valve body. Compressed gas (previously stored in the engine housing, the interior cavity of the threaded valve guide and the first axial cavity of the valve body) then rushes through the gap created between the valve head and the shoulder, forcing the valve to remain open until the gas is deployed. The gas rushes through the second axial cavity, past the valve stem guides, through the diffuser-receiving chamber and through the unobstructed, doughnut-shaped air passage in the diffuser. The gas achieves relatively laminar flow owing in part to the aerodynamic fins included in the diffuser. The gas then fills the space defined by the diffuser cup and the expansion cup of the piston, which rest near or against one another prior to gas forcing the two elements apart. The introduction of gas into this space forces the piston in the proximate direction, pushing the plunger through the interior of the housing and correspondingly forcing the fluid from the injector through the at least one orifice in the proximate end of the injector and into and/or through the injection surface. The piston and plunger act in concert as a driver. Once the plunger comes to rest against the proximate end of

the housing, excess gas may escape through the exhaust passage in the housing. The user may then dispose of the needle-less injector, the injection having been painlessly completed in silence.

While the description above refers to particular embodiments of the present invention, it should be readily apparent to people of ordinary skill in the art that a number of modifications may be made without departing from the spirit thereof. The accompanying claims are intended to cover such modifications as would fall within the true spirit and scope of the invention. The presently disclosed embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than the foregoing description. All changes that come within the meaning of and range of equivalency of the claims are intended to be embraced therein.